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(54) Title: GELLAN GUM DIPPED PRODUCTS

(57) Abstract: A dippable coating useful for dip coating tablet(s) comprising gellan gum is disclosed along with a process which comprises admixing gellan gum and water under effective shear conditions to prepare an aqueous gellan gum desirable dip coating composition thereof whereby the aqueous gellan gum coating composition is applied as by dipping, in an adherent fashion to a placebo or a tablet containing a pharmaceutical active drug ingredient such as aspirin or the like to form a gellan gum dip coated placebo or gellan gum dip coated active drug or gellan dip coated aspirin and the like.

GELLAN GUM DIPPED PRODUCTS

FIELD OF THE INVENTION

This invention relates to gellan gum dipped products. More particularly this invention relates to medicinal tablet product(s) which have been dipped in gellan gum or gellan gum blends.

BACKGROUND OF THE INVENTION

Tablets are typically used to deliver a pharmacologically effective amount of a therapeutic drug to humans and animals so as to provide medicinal benefit to the human or animal. Typically such therapeutically effective drugs include those active drugs that possess and produce desirable drug effects after effective consumption by the human or animal.

In medicinal uses, one or more coatings is desired on a medicinal tablet in order to obtain one or more of gloss, better appearance, identification, mouthfeel, stability, color, swallowability, improved taste and the like.

Gelatin is used as a tablet coating. Presently, gelatin based products are manufactured using several steps that require the tablets to be dipped into gelatin. Amidst the mad cow disease concerns, where potential use of gelatin may be in jeopardy, use of gellan and gellan blends to dip tablets are an alternative. Also, the gelatin-dipping process is a time-consuming process. By developing a gellan-based system, at least one dipping step is eliminated which is a cost savings.

Despite the aforementioned gelatin based products, a need exists in the industry for a process for preparing gellan gum dipped pharmaceutically acceptable dipped products. Even with the foregoing and other tablet coating and dipped compositions, the industry continues to desire a process and a product which provides enhanced tablet coating (dipped) properties.

OBJECTS OF THE INVENTION

It is an object of the invention to provide a gellan gum dipped product.

It is another object of the invention to provide a gellan gum dipped medicinal product.

It is yet an additional other objective of this invention to provide a process for preparing an acetaminophen tablet having a coating comprising gellan gum which has been provided by dipping acetaminophen into a dippable gellan gum composition.

It is an additional objective of this invention to provide a process for preparing a gellan gum composition useful for coating tablets by dipping.

It is still another objective of this invention to provide an improved process for preparing a gellan gum composition useful for dip coating acetaminophen and other active drugs.

It is yet another objective of this invention to provide a process for preparing a dip coated tablet such as a dip coated placebo or a dip coated pharmaceutical tablet comprising an active drug.

It is yet still an additional objective of this invention to provide a tablet having one or more enhanced properties such as higher gloss, better mouthfeel, non-tackiness, being swallowable with little or no accompanying liquid, better taste and the like.

It is yet another object to provide an improved process for preparing a gellan gum composition useful for dip coating acetaminophen and other active drugs.

The above objectives and other objectives are met in this invention which is more particularly described hereinafter without limitation.

SUMMARY OF THE INVENTION

This invention comprises a process for preparing a gellan gum dipped product, a gellan gum dipped product and a method of use for a gellan gum dipped product.

According to the process of this invention, a dippable gellan gum aqueous composition is prepared comprising gellan gum and a tablet (such as an active drug(s))having acceptability to the gellan gum present in the dippable gellan gum composition is contacted by dipping the tablet in the dippable composition. A dipped gellan gum product is thereby prepared. Further according to this invention, the dipped gellan gum product having a partial or complete coating resulting from the aforedescribed dipping is thereafter made available to a patient for consumption as by having the patient swallow the gellan gum dipped tablet.

DETAILED DESCRIPTION OF THE INVENTION

As used herein, gellan gum is that produced by inoculating a carefully formulated fermentation medium with the microorganism Sphingamonas elodea (ATTC 31461). Gellan Gum is available from Monsanto Company, 800 North Lindbergh Boulevard, St. Louis, Missouri 63167, USA. Typical brand names include KELCOGEL® and GELRITE®. Gellan gum useful herein includes any form available form such as but not limited to, non-clarified, clarified, and partially-clarified native, deacetylated, partially deacetylated forms as well as mixtures thereof and the like. Kelcogel® and Gelrite® are registered trademarks of Monsanto Company. Gellan gum may be prepared according to the methods disclosed in U.S. Patent 4,326,052 and 4,385,123 both of which are incorporated herein their entirety by reference.

The process for preparing a coated placebo or a coated (pharmaceutical) tablet comprising an active drug herein such as aspirin, ibuprofen and the like comprises the steps of admixing gellan gum and water under effective shear, heat and ionic conditions to prepare an aqueous gellan gum coating composition and applying the aqueous gellan gum coating composition in an effective fashion to a placebo or to a tablet such as one comprising a pharmaceutical whereby a gellan coated placebo or coated pharmaceutical tablet is formed. A drying step typically occurs and typically follows.

In particular this invention relates to an intact active tablet useful herein comprising an active drug (biologically active ingredient) such as but not limited to those selected from the group consisting of aspirin, naproxen sodium, acetaminophen, ibuprofen, celecoxib, oxaprozin, sildenafil citrate, alendronate sodium, mixtures thereof and the like and optimally an analgesic in combination with one or more of an antihistamine, antitussive, decongestant, and expectorant and mixtures thereof and the like, dip coated with gellan gum, a method to prepare a dip coated gellan gum

composition useful to effectively dip coat one or more of the aforementioned actives, mixtures thereof and the like, and to a method for effectively dip coating one or more of the aforementioned actives, mixtures thereof and the like, with gellan gum or blends thereof.

A dippable gellan gum composition of this invention comprises a gellan gum composition which is dippable, i.e., a composition which will accept a tablet dipped into it. In the practice of this invention a tablet is employed which physically can be dipped into a dippable gellan gum composition of this invention and upon removal of the dipped tablet from the gellan gum composition a portion (an effective amount) of the gellan gum from the gellan gum composition adheres to the dipped tablet to provide a partial or complete effective dip coating thereon.

The aqueous gellan gum coating composition useful to coat tablets such as aspirin, ibuprofen and the like is preferably admixed in any suitable container or the like prior to applying the gellan gum composition to or on a tablet to be coated. Initially the gellan gum and water are admixed and further mixing is carried out under effective shear to form an aqueous tablet coating composition. Typically the gellan gum coating aqueous composition prior to application of such effective shear will have a viscosity in the range from about 44 cps. to about 55,500 cps. and preferably from about 2200 to about 50,000 cps although gellan gum compositions having greater and lesser viscosities may sometimes be employed depending on a number of factors.

The temperature of the composition is typically in the range from about 25°-60°C although greater and lesser temperatures may be employed if desired as those of skill in the art will recognize after reading this specification.

If desired, gellan gum compositions comprising gellan gum and/or gellan gum and one or more of a another ingredient such as a polymer such as, but not limited to, those selected from the group consisting of hydroxypropyl celleulose, hydroxypropyl methyl cellulose, sodium carboxymethyl cellulose, sugar, aspartame, maltodextrin, tapioca dextrin, modified food starches, carrageenan, gum acacia, locust bean gum, xanthan gum, alginates, guar, corn syrup solids, polyvinylpyrrolidone, mixtures thereof and the like may be employed in this invention. As employed herein, the term "Gellan gum" includes gellan gum and/or compositions of gellan gum with one or more of these polymers or a sugar.

The aqueous gellan gum composition of this invention may be mixed in or by any suitable mixing system preferably until substantially complete mixing has been accomplished. Some heating may be necessary to achieve dispersion and hydration of gellan gum. The amount of shear preferably employed is an effective amount, i.e., which produces a well mixed homogenous gellan gum composition. The aforementioned admixing can be carried out by any convenient means including but not limited to use of a propeller or stirrer system although generally stirring by a convenient mechanical means is acceptable. Other forms of mixing can be employed.

Optionally, if desired, various other ingredients may be employed in the gellan gum aqueous composition include any ingredient which is compatible or can be made compatible with an aqueous gellan gum composition useful to coat tablets of this invention (such as, but not limited to, colors, color system(s), flavor(s), sweetener(s), mint(s), fragrance(s), plasticizer(s), polymers, hydrocolloids, active ingredient(s) and mixtures thereof and the like).

The gellan gum aqueous composition is preferably applied to the tablet(s) to be dip coated in a batch, semi-continuous or continuous process or some combination

thereof in a manner which produces a satisfactorily uniformly coated tablet. The gellan gum composition may be applied to tablets to be coated using any satisfactory application and drying system or combination of some application system and some drying system.

Typically the concentration of gellan gum in the dippable gellan gum composition of this invention ranges by weight from about 0.01 to about 10%, preferably from about 0.05 to about 5% and most preferred from about 0.1 to about 3%.

During application of the gellan gum aqueous composition to the tablet to be dip coated, the temperature of the gellan gum aqueous composition is preferably in the range from about 25°C to about 45°C although greater or lesser temperatures may be employed if desired. It is preferred that the gellan gum composition be maintained in a solution or dispersion or an applicable state during its coating application to the tablet(s) to carry out this invention.

Preferred tablets are medicinal tablets for humans or animals. The tablets include but are not limited to tablets of any convenient composition or shape which may or may not contain any pharmaceutically effective drug vitamin or nutrient or drugs suitable for human and/or animal consumption. A gellan gum dip coating may be employed on tablets which are placebos or blanks. Tablets useful herein include but are not limited to tablets which are uncoated or have been coated one or more times. In one embodiment a gellan gum coating may be the only coating and may comprise a first coating or a second or a third coating or dip coating.

Illustrative colors and colorants useful herein include without limitation, pigments, dyes, lakes and oxides (including titanium dioxide) and the like, may be optionally employed with gellan gum used in practicing this invention. The gellan gum

aqueous composition may optionally contain a suitable color or colorants for application to a colored or noncolored coated or uncoated tablet.

Tablets to be dip coated according to this invention may be colored, neutral or have their natural color or may be absent color. If one of more colors, dyes lakes, or pigments or mixtures thereof are employed in a gellan gum coating composition herein, such as for example, an FDA certified color, dye, lake, or pigment, the color or combination of colors is not critical and may be selected by those of skill in the art based upon a need at the time of the coating operation. Examples of suitable pigments which are useful in this invention include, without limitation, FD&C and D&C lakes, titanium dioxide, magnesium carbonate, talc, pyrogenic silica, iron oxides, channel black, insoluble dyes and mixtures thereof and the like. Also, nature pigments such as riboflavin, carmine 40, curcumin, annatto, mixtures thereof and the like are acceptable herein. Other examples of pigments suitable herein include, without limitation, these disclosed in Jeffries U.S. Patent No. 3,149,040 and Butler et al., U.S. Patent 3,297,535, as well as in Colorcon U.S. Patent No. 3,781,984. These three patents are incorporated herein by reference in their entirety. In the absence of a colorant, the gellan gum composition typically produces a clear or substantially clear coating on a coated tablet.

Typically the concentration of gellan gum in the dippable gellan gum composition of this invention ranges by weight from about 0.01 to about 10%, preferably from about 0.05 to about 5% and most preferred from about 0.1 to about 3%.

As employed herein, the term "tablet" includes without limitation, tablet, particle, micronized particle, particulate, pellet, pill, core, powder, granule, granulate, small mass, seed, specks, spheres, crystals, beads, agglomerates, mixtures thereof and the like. Typically the preferred tablet will be in a form sufficiently stable physically and chemically to be effectively coated in a system which involves some movement of the

tablet, as for example in a fluidized bed, such as in a fluidized bed dryer or a side vented coating pan, combinations thereof and the like. Virtually any tablet, placebo, the latter typically lactose or sugar or mixtures thereof and the like, is acceptable herein as a tablet to be coated in the practice of this invention.

The application of the gellan gum aqueous composition as a coating to the tablet is preferably carried out by placing a tablet capable of receiving and adhering an effective amount of a gellan gum tablet coating composition of this invention in any acceptable coating application system. An acceptable coating application system is illustratively any system which has the capability to apply an effective gellan gum coating composition of this invention to a tablet to provide an effectively, preferably uniformly dip coated tablet.

A preferred method of coating includes coating tablet(s) first with a colored base (for example spraying a yellow color onto the tablet) and then applying a clear gellan gum top coat. The tablets are then dipped (one end only) into a pigmented system and then again (for example a red color) and dried. The tablet can then be dipped into a clear gellan gum solution and allowed to dry. Additionally, the tablet can be dipped a second time and allowed to dry.

An effective amount of time is typically employed during the dipping process. Dipping may be carried out by hand, machine or any convenient dipping method.

The gellan gum dip coated tablets of this invention may be internally consumed by humans and animals in a typical customary manner such as by swallowing, so that the biologically active dip coated drug is made available to the patient.

Gellan gum (amount in formula) is typically in the range by weight from about 0.01% to about 10% and preferably from about 0.05% to about 5% and most preferred from about 0.1% to about 3%.

Plasticizers useful herein if desired include but are not limited to: Propylene glycol, polyethylene glycol, glycerin, triacetin (glyceryl triacetate), acetyltriethyl, citrate, triethyl, citrate, tributycitrate or acetyltributlcitrate, Plas 2 (combination of Glycerolmonosterate, triethylcitrate and Polysorbate 80). Plasticizers if used are generally in the range by weight from about 0% to about 5% and preferably from about 1.0% to about 3.0% and most preferred from about 0.25% to about 0.75%.

Adhesion aids useful herein include but are not limited to: Lecithin, polyols, such as sorbitol, maltitol, mannitol, sylitol. Typically, adhesion aids maybe used (if desired) in the range by weight from about 0% to about 5% and are preferred in the range from about 1.0% to about 3.0% and are most preferred from about 0.25% to about 0.75%.

Secondary polymers/hydrocolloids, useful herein include (if desired) but are not limited to Carrageenan, Gum Acacia, Locust Bean Gum, Xanthan Gum, Alginates, Guar, Corn Syrup Solids, hydroxypropyl methylcellulose (HPMC), Hydroxpropyl cellulose (HPC), lactose, Polyvinylpyrrolidone (PVP), Sodium carboxymethylcellulose (NaCMC), maltodextrin, dextrin, dextrose, polydextrose, polyvinyl alcohol (PVA). Typically, these may be useful in weight ranges from about 0% to about 5% and maybe preferably used from about 1.0% to about 3.0% and most preferred from about 0.25% to about 0.75%.

Examples are provided to illustrate the preparation of acceptable dip coated tablets in accordance with this invention and are provided by way of illustration

and are not intended to limit the invention in any way. All percents and any parts are by weight unless otherwise indicated. These Examples illustrates the practice of this invention in a non limiting fashion.

The following Examples are intended to provide detail about this invention and are not meant to limit this invention in any way.

EXAMPLES

Example #1: Preparation of dippable gellan gum composition:

A gellan gum composition useful for dip coating tablets was prepared comprising 30 grams gellan gum, 1968 grams water and two grams sodium citrate to provide a 1.5% by weight gellan gum aqueous composition useful for coating tablets.

This aqueous dippable gellan gum composition was prepared by weighing the water into a clean dry residue free beaker and weighing out the gellan gum (Kelcogel) and sodium citrate. The water was then mixed with a laboratory mixer to create a vortex. The gellan gum powder and sodium citrate was slowly introduced into the vortex to achieve dispersion. Stirring was continued without heat to finalize the dispersion of gellan gum. Heat was applied while stirring until the dispersion temperature was about 70°C to hydrate the gellan gum. Care was taken to avoid charring the resulting dispersion, i.e. employing sufficient stirring and avoiding overheating. The beaker was removed from the stir plate and cooled to ambient temperature to make gellan gum aqueous composition(s) available for dip coating hereinafter.

The drug active(s) and coating process described and other inventive concepts in U.S. Patent Application No. 09/416,181 filed October 11, 1999 "COATED

ACTIVE TABLET(S)" John Flanagan et al., are useful herein and this patent application (09/416,181) is incorporated herein in its entirety by reference.

A coating process was carried out similar to that disclosed above and using components similar thereto.

Step 1: Coat tablet with yellow base coat and gellan clear topcoat #1:

420 grams of capsule shaped Acetaminophen tablets (1.5 cm LX 0.7 cm WX 0.6 cm H) were coated with a yellow gellan base coat (2.0% weight gain) and with a clear gellan top coat #1 (0.10% weight gain) using a fluidized system similar to an Aeromatic Strea 1 (Niro Inc., 9165 Rumsey Road, Columbia, MD 21045 USA).

Step 2: Dip half the tablet into a red gellan system:

Heat red gellan system, while stirring, to 50-55 degrees C. Place a tablet into the end of a trimmed-off plastic pipette (or suitable tablet holder). Dip tablet from Step 1 into red gellan system and shake off excess. Repeat Step with several tablets.

Step 3: Drying

Place tablets, one per plastic pipette, into a metal cylinder, exposed to the bottom of the fluidized coating system. Tablets are heated at 120-130 degrees F until dry (5-10 minutes).

Repeat Step 3 with several tablets.

Step 4: Single dip-using gellan clear (for dipping) #1:

Heat gellan clear (for dipping) #1 while stirring, to 50-55 degrees C. Dip red end of tablet into gellan clear formula. Shake off excess.

Step 5: Drying

Follow same procedure as in Step 3

Example #2: Dip both ends of tablet:

Utilize same procedure/steps as in Example 1 with the following exception:

Repeat Step #4 and 5 gain using yellow end of the tablet.

Example #3: Repeat dip step for a double dip of red end of the tablet:

Utilize same procedure/steps as in Example 1 with the following exceptions:

Repeat step #4 and 5 again using red end of the tablet.

Example #4: Use less weight gain for yellow base coat:

Use same procedure/steps as in Example 1 with the following exceptions:

Step 1: 1.0% weight gain of yellow gellan base coat used.

Example #5: Use different topcoat:

Utilize same procedure/steps as in Example 1 with the following exceptions:

Step 1: Use Gellan Clear Topcoat #2

Example #6: Use different gellan clear (for dipping) #2:

Utilize same procedure/steps as in Example 1 with the following exceptions:

Step 4: Use gellan clear (for dipping) #2

Step 5: Dry tablets at 160-170 degrees F

Example #7: Use different gellan clear (for dipping) #3:

Utilize same procedure/steps as in Example 1 with the following exceptions:

Step 4: Use gellan clear (for dipping) #3

Step 5: Dry tablets at 160-170 degrees F

Example #8: Gellan clear sprayed onto tablets instead of gellan clear dipping step:

Step 1: Coat tablet with white gellan base coat (no clear topcoat is applied):

420 grams of capsule shaped Acetaminophen tablets (1.5 cm L X 0.7 cm W X 0.6 cm H) were coated with a white gellan base coat to a 2.0% weight gain using a fluidized system similar to an Aeromatic Strea 1 (Niro Inc).

Step 2: Dip half the tablet into a red gellan system:

Heat red gellan system, while stirring, to 40 degrees C. Place 3 tablets into a clamp (or suitable tablet holder) and dip tablet from Step 1 into red gellan system, remove dipped tablet from gellan gum system, and shake off excess. Repeat Step 2 with several tablets.

Step 3: Drying

Place tablets (3 per clamp) onto metal arms suspended above column clamp, (or suitable tablet holder) which is placed directly in the center of the airflow to enhance drying. Tablets are heated at 190-200 degrees F until dry (5-10 minutes). Repeat Step 3 with several tablets.

Step 4: Spraying gellan clear:

Coat tablets from Step 3 (along with uncoated placebos for a total charge of 420 grams) to a 0.5% weight gain using Gellan Clear Topcoat #2.

Example #9: White HPMC base coat:

Utilize same procedure/steps as in Example 1 with the following exceptions:

Step 1: Use white HPMC base coat, no clear topcoat applied

Step 4: Use different gellan clear (for dipping) #4

Example #10: Gellan with Carrageenan blend:

Utilize same procedure/steps as in Example 4 with the following exceptions:

Step 4: Use gellan blend (for dipping) #4

Example #11: Gellan with Gum Acacia blend:

Utilize same procedure/steps as in Example 4 with the following exceptions:

Step 4: Use gellan blend (for dipping) #5

Example #12: Gellan with Locust Bean Gum blend:

Utilize same procedure/steps as in Example 4 with the following exceptions:

Step 4: Use gellan blend (for dipping) #6

Example #13: Gellan with Xanthan Gum blend:

Utilize same procedure/steps as in Example 4 with the following exceptions:

Step 4: Use gellan blend (for dipping) #7

Utilize same procedure/steps as in Example 4 with the following exceptions:

Example 14

Step 2: Use red gellan blend system

Yellow Gellan Base Coat:

Raw Material:	%	Grams
Deionized Water	96.66	966.60
Gellan Gum (Kelco)	1.50	15.00
0.74% Yellow Dispersion (Warner-Jenkinson)	0.74	7.40
0.45% Propylene Glycol (Baker)	0.45	4.50
0.45% Epikuron P100 (Lucas Meyer, Inc.)	0.45	4.50
Sodium Citrate Dihydrate (Baker)	0.10	1.00
Methyl Paraben (Spectrum)	0.10	1.00
	100%	100 grams

Yellow Dispersion:

Raw Material:	%	Grams
Titanium Dioxide	38.00	38.00
D&C Yellow No. 10 Lake, 16%	2.00	2.00
EFG, Food Grade EDTA (40%)	0.50	0.50
EDTA (10%)	7.00	7.00
Deionized water	52.50	52.50
	100%	100 grams

Results:

Examples 1-7 and 9-14 exhibited good gloss and tablet smoothness.

Example 8 exhibited excellent gloss and tablet smoothness. Some minimal red color transferred to white part of tablet.

HPMC White Base Coat

Raw Material:	%	Grams
Distilled Water	13.60	17.00
Pharmacoat 606 (Shinitsu)	80.00	100.00
HPMC White Dispersion	4.80	6.00
Polyethylene Glycol 400	1.60	2.00
	100%	125 grams

HPMC White Dispersion:

Raw Material:	%	Grams
Distilled Water	39.50	79.00
Pharmacoat 606	10.00	20.00
Titanium Dioxide	50.00	100.00
Food Grade EDTA (40%)	0.50	1.00
	100%	200 grams

White Gellan Base Coat:

Raw Material:	%	Grams
Deionized Water	95.95	383.80
Gellan Gum (Kelco)	2.00	8.00
HPMC White Dispersion	0.99	3.96
Propylene Glycol (Baker)	0.40	1.60
Epikuron P100 (Lucas Meyer, Inc.)	0.40	1.60
Sodium Citrate Dihydrate (Baker)	0.13	0.52
Methyl Paraben (Spectrum)	0.13	0.52
	100%	400 grams

Gellan Clear Topcoat #1:

Raw Material:	%	Grams
Deionized Water	97.70	195.40
Gellan Gum	1.50	3.00
Sodium Citrate Dihydrate (Baker)	0.10	0.20
Methyl Paraben (Spectrum)	0.10	0.20
Propylene Glycol (Baker)	0.6	1.2
	100%	200 grams

Gellan Clear Topcoat #2

Raw Material:	%	Grams
Deionized Water	97.70	195.40
Gellan Gum	1.50	3.00
Epikuron P100	0.45	0.90
Polyethylene Glycol 400 (Spectrum)	0.15	0.30
Sodium Citrate Dihydrate (Baker)	0.10	0.20
Methyl Paraben (Spectrum)	0.10	0.20
	100%	200 grams

Red Gellan System:

Raw Material:	%	Grams
Deionized Water	94.62	189.24
Gellan Gum	2.00	4.00
Epikuron P100	0.60	1.20
Sodium Citrate Dihydrate (Baker)	0.14	0.28
Methyl Paraben (Spectrum)	0.14	0.28
FD&C Red No. 40 Lake, 38%	1.30	2.60
Propylene Glycol	1.20	2.40
	100%	200 grams

Red Gellan Blend System:

Raw Material:	%	Grams
Deionized Water	95.10	95.10
Gellan Gum	1.50	1.50
Carrageenan (Colloid 710, TIC Gums, Inc.)	0.50	0.50
Epikuron P100	0.20	0.20
Sodium Citrate Dihydrate (Baker)	0.10	0.10
Methyl Paraben (Spectrum)	0.10	0.10
FD&C Red No. 40 Lake, 38%	1.30	1.30
Propylene Glycol	1.20	1.20
	100%	100 grams

Gellan Clear (for dipping) #1:

Raw Material:	%	Grams
Deionized Water	97.70	195.40
Gellan Gum	1.50	3.00
Sodium Citrate Dihydrate (Baker)	0.10	0.20
Methyl Paraben (Spectrum)	0.10	0.20
Propylene Glycol (Baker)	0.60	1.20
	100%	200 grams

Gellan Clear (for dipping) #2

Raw Material:	%	Grams
Deionized Water	98.30	196.60
Gellan Gum	1.50	3.00
Sodium Citrate Dihydrate (Baker)	0.10	0.20
Methyl Paraben (Spectrum)	0.10	0.20
	100%	200 grams

Gellan Clear (for dipping) #3

Raw Material:	%	Grams
Deionized Water	97.42	194.84
Gellan Gum	1.50	3.00
Maltitol Syrup (Lycasin 85%-Roquette)	0.50	1.00
Epikuron P100	0.23	0.46
Propylene Glycol (Baker)	0.15	0.30
Sodium Citrate Dihydrate (Baker)	0.10	0.20
Methyl Paraben (Spectrum)	0.10	0.20
	100%	200 grams

Gellan Blend (for dipping) #4:

Raw Material:	%	Grams
Deionized Water	97.76	97.76
Gellan Gum	1.00	1.00
Carrageenan (Colloid 710, TIC Gums, Inc.)	0.50	0.50
Propylene Glycol (Baker)	0.60	0.60
Sodium Citrate Dihydrate (Baker)	0.07	0.07
Methyl Paraben (Spectrum)	0.07	0.07
	100%	100 grams

Gellan Blend (for dipping) #5

Raw Material:	%	Grams
Deionized Water	97.74	97.74
Gellan Gum	1.25	1.25
Gum Acacia (Spectrum)	0.25	0.25
Propylene Glycol (Baker)	0.60	0.60
Sodium Citrate Dihydrate (Baker)	0.08	0.08
Methyl Paraben (Spectrum)	0.08	0.08
	100%	100 grams

Gellan Blend (for dipping) #6		
Raw Material:	%	Grams
Deionized Water	97.74	97.74
Gellan Gum	1.25	1.25
Locust Bean Gum (Spectrum)	0.25	0.25
Propylene Glycol (Baker)	0.60	0.60
Sodium Citrate Dihydrate (Baker)	0.08	0.08
Methyl Paraben (Spectrum)	0.08	0.08
	100%	100 grams

Gellan Blend (for dipping) #7		
Raw Material:	%	Grams
Deionized Water	97.74	97.74
Gellan Gum	1.25	1.25
Xanthan Gum (Xantural 75, Kelco)	0.25	0.25
Propylene Glycol Dihydrate (Baker)	0.6	0.6
Sodium Citrate Dihydrate (Baker)	0.08	0.08
Methyl Paraben (Spectrum)	0.08	0.08
	100%	100 grams

Notes:

Step 1: The fluidized system is similar to Aeromatic Strea 1 of Niro Inc.

Step 2: A hot plate is used to heat the red gellan system. The tablet is being dipped into this solution. At this point, the tablet is shaken to remove excess red but is still wet. The tablet is then dried in Step 3.

Step 3: The fluidized system's base is used as a drying source but the tablets are placed around it - no tablets are fluidized/coated here. The equipment is a source of heat to dry the tablets.

Yellow is the pigmented yellow gellan system - see page 3, 1st formula - Yellow Gellan Base Coat (1st formula listed after Example t#14).

Red is on page 5 - Red Gellan System (2nd from top).

All formulations are listed together and then referenced throughout the examples. After example 1, for each of the rest of the examples, the formula used should be stated by name - for example, gellan clear (for dipping) #3, red gellan brand system, etc.

Grain Processing Corp.
Muscatine, IA 52761

Spectrum Quality Products, Inc.
Gardena, CA 90248

J.T. Baker
A Div of Mallinckrodt Baker, Inc.
Phillipsburg, NJ 08865

Lucas Meyer, Inc.
P.O. Box 3218
Decatur, IL 62524

		wt	
	TiO_2	38.0	
	EFG	2.0	
	EDTA (10%)	.5	40% solids
5	H_2O DI	52.5	
		100g	

			wt
	Water DI	96.66	1449.9
10	Kelcogel Lt #68014A	1.5	22.5
	NA Citrate Dihydrate (Baker Lt #M02646)	.1	1.5
	Methylporaben (Spectrum Lt #MP0267)	.1	1.5
	Yellow (NB# 59688A) (40%)	.74	11.1
	Epikuron (Lucas Meyer Lt #34565)	.45	6.75
15	PG (Baker LT #M18H02)	.45	6.75
			1500g

		wt	
	Water DI	65.2	
20	Y-6 (Dye)	9.2	
	TiO_2	13.3	40% solids
	R-40B (HDL)	22.5	
	EFG	2.3	
		112.5g	

25

		wt
Water DI	96.96	484.8
Kelcogel Lt #68014A	1.5	7.5
NA Citrate Dihydrate (Baker Lt #M02646)	.1	.5
Methylporaben (Spectrum Lt #MP0267)	.1	.5
Red (Solution NB# 59681A)	.74	3.7
Epikuron 100 (Lucas Meyer Lt #34565)	.3	1.5
Propylene Glycol (Baker TS 12-21-99 LT# M18H02)	.3	1.5
		500 g

@ RT- Solution gelled

Thus, it is apparent that there has been provided, in accordance with the instant invention, an invention that fully satisfies the objects and advantages set forth herein above. While the invention has been described with respect to various specific examples and embodiments thereof, it is understood that the invention is not limited thereto and many alternatives, modifications and variations will be apparent to those skilled in the art in light of the foregoing description. Accordingly, it is intended to embrace all such alternatives, modifications and variations as fall within the spirit and broad scope of the invention.

WHAT IS CLAIMED IS:

1. A pharmaceutical tablet coated with a dipped coating comprising gellan gum.

2. The dipped tablet coating of claim 1 wherein said gellan gum is present in an amount from about 0.025% to about 10% by weight of the total tablet and said tablet is a biologically active drug.

3. The tablet coating of claims 1 or 2 wherein said gellan gum is present in an amount from about 0.05% to about 5% by weight of the total tablet.

4. The tablet coating of claims 1, 2 or 3 wherein said gellan gum is present in an amount from about 0.075% to about 3% by weight of the total tablet.

5. The tablet coating of claims 1, 2 or 3 wherein said coating further comprises a color and the tablet comprises an active drug.

6. The tablet coating of claims 1, 2 or 3 wherein said coating further comprises a plasticizer, or a surfactant.

7. The tablet coating of claims 1, 2 or 3 wherein said coating comprises gellan gum and is the primary coating.

8. The tablet coating of claim 1 where said coating comprises a polymer other than gellan gum as the primary coating and gellan gum is the secondary coating.

9. The tablet coating of claim 1 wherein said coating comprises gellan gum and is the only coating.

10. The tablet coating of claim 1 wherein said primary coating comprises gellan gum and a color and said secondary coating comprises gellan gum.

11. A process for preparing a dip coated tablet which process comprises the steps:

a. admixing gellan gum and water under shear to prepare an aqueous gellan gum dippable coating composition useful for dip coating a tablet(s) and

b. applying an effective amount of said aqueous coating composition in an adherent fashion to a tablet capable of accepting a dip coating whereby said dip coated tablet is formed and (optionally) drying said dip coated tablet to form said dip coated tablet.

12. The process of claim 11 wherein said aqueous gellan gum coating composition is applied once or more than once to a tablet.

13. The process of claim 12 wherein said aqueous coating composition comprises a color and said tablet comprises an active drug.

14. The process of claim 13 wherein a coating of a polymer other than gellan gum is applied to said tablet prior to application thereof of said aqueous gellan gum coating composition.

15. The process of claim 14 wherein said polymer is in combination with gellan gum.

16. The process of claim 15 wherein more than one coating is applied to a tablet and said coating is selected from the group consisting of gellan gum and another polymer.

17. The process of claim 16 wherein said tablet of claim 11 is dip coated.

18. The process of claim 17 wherein said applying is carried out by applying said aqueous gellan gum composition by mechanical means whereby said aqueous composition is directed to said tablet to be coated.

19. A gellan gum product suitable for forming dip coated tablet comprising gellan gum in an amount of about 0.1% to about 10% and having a viscosity of about 44 cps to about 55,000 cps prior to application to said tablet.

20. The gellan gum product of claim 19 wherein said gellan gum is present in an amount from about 0.25% to about 5% weight.

21. The gellan gum product of claim 20 wherein said gellan gum is present in an amount from about 0.075% to about 3% weight.

22. The gellan gum product of claim 19 wherein said coating comprises an active ingredient.

23. The gellan gum product of claim 19 wherein said coating comprises a plasticizer.

24. A method of treating a patient (or animal) which comprises effectively administering to said patient a therapeutically effective amount of a dip coated tablet, wherein said coated tablet comprises a tablet dip coated with gellan gum and said tablet further comprises a therapeutically effective amount of active drug beneficial to said patient.

25. The method of claim 24 wherein said dip coated tablet comprises gellan gum which is present in an amount from about 0.025% to about 10% of the total tablet weight and wherein such treatment is oral or rectal.

26. The method of claim 25 wherein said gellan gum is present in an amount from about 0.05% to about 5% of the total tablet weight.

27. The method of claim 26 wherein said gellan gum is present in an amount from about 0.075% to about 3% of the total tablet weight.

28. A tablet dip coating composition comprising gellan gum in an effective amount which is prepared by admixing gellan gum and water under effective shear to prepare an aqueous gellan gum coating composition useful for dip coating a tablet(s) and which has a dip coating which adheres effectively thereto in an effective amount.

29. The tablet coating composition of claim 28 wherein said amount of gellan gum is from about 0.025% to about 10% by weight.

INTERNATIONAL SEARCH REPORT

Inter. ...nal Application No
PCT/US 01/03287

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K9/28 A61K9/20

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
WPI Data, PAJ, EPO-Internal, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99 46329 A (WARNER-LAMBERT) 16 September 1999 (1999-09-16) claims 1,2,4,7,13,23	1-7,9, 11-16, 18-29

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 June 2001	29/06/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Ventura Amat, A

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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter. ...nal Application No
PCT/US 01/03287

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9946329 A	16-09-1999	FR 2775979 A	17-09-1999
		AU 2785199 A	27-09-1999
		EP 1062274 A	27-12-2000